

President

R. D. (Dan) SOWARDS TX Dept. of Health 1100 W. 49th Street Austin, TX 78756-3189 (512) 719-0243 FAX (512) 719-0263 dan.sowards@tdh.state.tx.us

President-Elect

STEVE STEINHOFF
WI Dept. of Agriculture
Box 8911
Madison, WI 53708
(608)224-4701
FAX (608)224-4710
steinsb@wheel.datcp.
state.wi.us

Vice-President

R. D. (Doug) SAUNDERS VA Dept. of Agriculture 1100 Bank Street, Rm 502 Richmond, VA 23219 (804) 786-8899 FAX (804) 371-7792 risaunders@vdacs.state.va .us

Secretary-Treasurer

TERENCE MACAIG VT Dept. of Health Env. Health Division P.O. Box 70 Burlington, VT 05402 (802) 863-7227 FAX (802) 863-7425 tmacaig@vdh.state.vt.us

Director of Public Policy BETSY B. WOODWARD 1238 Sedgefield Road Tallahassee, FL 32311 (850) 878-7440 FAX (850) 878-1763 betsy_ woodward@hotmail.com

Training Director

JAMES L. SEVCHIK 8057 Highland Farms Dr. East Amherst, NY 14051 (716) 636-0409 jsevchik@msn.com

Executive Director
DENISE C. ROONEY
Association of Food and
Drug Officials
P.O. Box 3425
York, PA 17402
(717) 757-2888
FAX (717) 755-8089
afdo@blazenet.net

Association of Food and Drug Officials

P.O. Box 3425 • York, PA 17402 Telephone (717)757-2888 • Fax (717)755-8089 E-Mail • afdo@blazenet.net

| April 19, 2000 | N → 1 |
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| Dockets Management Branch (HFA-305) Docket No. 98-045N3 (USDA/FSIS) and 00N-0504 (FDA) | 701 |
| U.S. Food and Drug Administration | 8 |
| 5630 Fishers Lane, Room 1061 Rockville, MD 20852 | |
| RE: Egg Safety Action Plan | 20 P/2 |
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The Association of Food and Drug Officials Board of Directors, hereinafter referred to as AFDO, is pleased to offer comments on the Food and Drug Administration's (FDA) and Food Safety and Inspection Services' (FSIS) notice for comments relative to the President's Council on Food Safety 's Egg Safety Action Plan announced by the President on December 11, 1999 which is to address Salmonella enteritidis (Se) contamination of shell eggs from production to consumer use.

AFDO is a 104 year old organization that represents federal, state, and local government regulatory officials and industry associates, many of whom are now actively involved with food safety efforts focusing on the safety of eggs. It is clear to AFDO that these officials believe that government intervention into production, processing, storage, shipping and distribution of eggs is the appropriate response needed at the present time. AFDO submitted comments on the Notice of Proposed Rulemaking with respect to regulation of shell eggs so as to reduce or eliminate Se in eggs. Those comments of September 1, 1999, Docket No. 98N-1230 and 98-045N2 are incorporated by reference for background information. The following comments provide further information and input with respect to the current Docket Announcement and Public Meetings.

1. The proposed Action Plan is very comprehensive and appears to address the areas of concern with respect to Se in shell eggs. Although FDA and FSIS have stated that the Plan will be modified with time, it is imperative that this Plan be considered a "work in progress" and that it maintains the flexibility required to incorporate emerging sound scientific information with respect to Se control measures in a timely manner.

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AFDO supports national uniform mandatory standards that would subject all eggs to the same safety standards across the US, backed by federal funding on an ongoing basis. AFDO strongly feels that continued federal funding is necessary for the success of this Action Plan. National standards are beneficial because they provide egg producers and packers with a level playing field industry—wide. Ideally, national safety standards should apply to all egg producers and packers, both big and small. Current USDA rules exempt producer/packers with 3,000 birds or less (approximately 2% of the eggs produced) from many requirements, including refrigeration. We believe that small businesses should not be completely exempt from the Egg Safety Action Plan. However, mechanisms must be identified to assist small producers so that critically identified safety requirements can be handled in a practical manner.

The proposed Egg Safety Action Plan outlines two basic options. Strategy I involves extensive on-farm testing for Se. Strategy II requires a kill-step during processing such as in-shell pasteurization. Given only these two basic options, the cost associated with on-farm testing or in-shell pasteurization may pose a significant hardship for small egg producers and packers. As an alternative for small businesses, we recommend requiring other HACCP-based components of the plan related to basic sanitation, rodent and pest control, employee hygiene and health, safety of water and food packing materials, washing, sanitizing and packaging. Without on-farm testing or in-shell pasteurization, sales could be limited to retail outlets and carry required "precautionary" handling or "warning" labels. Sales to restaurants, hospitals, nursing homes, schools, daycare or other institutions (where the risk is greater) could be prohibited.

- 3. Training/education represents an essential component of the Plan and must be broadly directed to reach the greatest percentage of the general population as well as the regulatory officials. Uniform and effective implementation relies on adequate resources for personnel training. Also of great importance for education and training are the retail/food service and consumer audiences. Multiple training/education strategies will be needed, and is especially importance for at-risk segments of the population and those portions of the industry that deal with those at-risk segments. Objective 2.2 provides a comprehensive listing of establishments, and Objectives 8.2.2 through 8.2.5 identify some of the most important at-risk populations to target for significant training/education/communication efforts.
- 4. The identified components presented in question 4 are equally important to ensure an environmentally controlled facility with respect to Se contamination prevention. However, the plan does not address a linkage between this Plan and the National Poultry Improvement Plan. Would such a linkage be advantageous?

- 7. If an environmental sample is positive, it should trigger flock testing.
- 9. If Se positive eggs are diverted for pasteurization, they should be under strict bio-security to preclude contamination of transportation vehicles, plant and other exposed environments. It addition, that control should extend to the shells and losses after cracking to preclude environmental contamination of refuse sites.

AFDO finds Objective 1.1.7 confusing. If eggs are diverted for a positive Se finding, why is provision provided for sale as shell eggs. This is assuming that the positive Se findings were based on analysis of eggs or flocks. Are the agencies considering a statistical sampling of eggs from infected flocks that will free the eggs from diversion? This is not clear and needs to be!

Objective 1.3 needs to emphasize the critical importance of prerequisite programs more strongly.

AFDO feels that Objective 2.2 identifying and addressing barriers to implementing the Food Code provisions in the listed facilities is imperative. If Food Code provisions cannot be effectively implemented in such facilities, those segments of the population utilizing these facilities have inadequate food safety protection at points where they are needed most.

AFDO hopes that there is strong linkage and communication between Objectives 3 and 4 and that there is a mechanism of timely sharing of human and feed/animal phage types on an ongoing basis in a common or linked database so that activities to achieve the goals of this Plan can be adjusted to situations and emerging science developed in such surveillance systems.

AFDO strongly supports the Objective 6. It is imperative that national Action Plans involving a strong state component such as this Plan, actively seek state input and resource needs for implementation. AFDO's vision of a truly integrated food safety partnership will assist in meeting this objective.

The importance of research needs identified in Objective 7 cannot be understated. Obviously implementation of this plan will be costly and research is necessary to ensure that those dollars are effectively utilized and achieve a measurable improvement in Se reduction/elimination in shell eggs. Sound science through these research needs will enable that to happen.

Finally AFDO would like to again stress the need for funding of State programs if the federal agencies are going to rely on State programs to do the environmental/producer level inspections. Many State programs do not currently have this component in their programs and have been relying on either the federal agencies to act, or have been involved only in traceback sampling on the farms following an outbreak. Without adequate funding and training the Egg Action Plan will not work.

AFDO thanks FDA and FSIS for the opportunity to comment on this important document and again reiterates the incorporation of our original comments September 1, 1999, to Docket No. 98N-1230 and 98-045N2. AFDO looks forward to continuing to work with FDA and FSIS on this issue.

Sincerely,

R. D. (Dan) Sowards, President

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Association of Food and Drug Officials

Betsy B. Woodward, Director of Public Policy

Association of Food and Drug Officials

cc: AFDO Board of Directors

AFDO Regional Affiliate Presidents

Ms. Denise Rooney

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